


Project Name / Design		E Microtix 4 & 50 PIL Picasso	
New Component / Item Code	LN515403	ArtWorks ID	EMEA_2020_00028310_000
Old Component / Item Code	LN515402	Languages	Ireland
Product / Eurocode / Mat. ID Code	8715104 & 5238409 / 18-0584	Job / Version No.	401994370_r0
		Date	04-08-2020

Black

LITHO OFFSET

REPRESENTATION:  Colours represented with a diagonal line have been modified to aid PDF approval.

MANUFACTURING SITE

Reference	NOTF011	Security Code / ICFP	515403
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FONTS

Body Copy Size	12.0pt
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TECHNICAL DETAILS

Component	Leaflet	Plant	Delpharm Orléans		
Dimensions	240 x 270 mm	Master Dieline	JJDEL_00049_V1	Date	27-03-2020

Profile Text Limit Bleed Fold/Technical Perforation Stamping Area

Diagram illustrating various security features:

- Coding (Silent Zone)
- Print & Varnish Free
- Print Free
- Varnish Free
- Seal Area
- Tamper Evident Label



Braille Grid



SCHAWKI

SCHAWK!

microlax

Rectal Solution

Sodium Citrate 450 mg / 5 ml

Sodium Lauryl Sulphoacetate 45 mg / 5 ml

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription.
- However you still need to take Microlax carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please talk to your doctor or pharmacist.

In this leaflet

1. What Microlax is and what it is used for.
2. Before you use Microlax
3. How to use Microlax
4. Possible side effects
5. How to store Microlax
6. Further information

1. What Microlax is and what it is used for

MicroLax enema is a laxative used to empty the large bowel in constipation, or prior to surgical and diagnostic procedures or in obstetrics prior to delivery. The enema acts as a laxative by softening the stools and by its lubricating properties.

This medicine is for use in adults and children.

2. Before you use Microlax

This medicine is suitable for most children and adults but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use this medicine...

If you have ever had a hypersensitivity reaction (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients. See Section 6.

⚠ Take special care with Microlax...

If you have ulcers or inflammation of your large

bowel or any other part of your intestine.

Prolonged use may lead to irritation of the anal canal.

The nozzle should only be inserted to half its length when used in children under 3 years old.

Seek medical advice if symptoms persist and avoid prolonged use. Speak to your doctor or pharmacist before using Microlax if you are taking sodium polystyrene sulphonate (a medicine used to treat high blood levels of potassium).

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before using this product if you are pregnant or breast-feeding.

Driving and using machines

Microlax has no effect on the ability to drive or use machinery.

⚠ Important information about some of the ingredients of Microlax

Microlax contains sorbic acid which may cause local skin reactions, e.g. contact dermatitis which is a local irritation at the site of use.

3. How to use Microlax

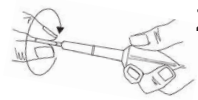
Check the information below to see how much medicine to use.

- Do not use more medicine than shown in the instructions below.
- **DO NOT** swallow this Microlax enema.

Age	Dose
Adults and children 3 years and older	The contents of one enema administered in the rear passage as necessary. See instructions on how to use enema below.
Children under 3 years	The contents of one enema administered in the rear passage as necessary. See instructions on how to use enema below Note: In children under 3 years, insert only half the length of the nozzle.

- Microlax is usually effective within 5 to 15 minutes.

Picture 1



1. Twist the seal of the nozzle (picture 1).
2. Squeeze the tube slightly so that a drop of Microlax smears the tip and thus makes insertion easier.
3. Insert the nozzle fully into the rectum. **N.B. In children under 3 years of age, insert only half the length of the nozzle** (see indication on the nozzle).

Picture 2



4. Squeeze out the contents fully by squeezing the shoulder of the tube. (picture 2)
5. Withdraw the nozzle still squeezing tightly.

⚠ If anyone has used too much or swallowed this product

If anyone has used too much or has accidentally swallowed Microlax, contact a doctor or your nearest Accident and Emergency department (Casualty), taking this leaflet and pack with you.

4. Possible side effects

Like all medicines, Microlax can cause side effects, although not everybody gets them.

- Prolonged use of Microlax may lead to irritation of the rear passage. Sensitivity reactions (such as a rash) rarely occur.
- Abdominal pain.
- Anal discomfort.
- Diarrhoea.
- Allergic reactions (e.g. hives).

If you experience any reactions to Microlax, discontinue using the product and speak to your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971, Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Microlax

Do not store above 25°C.

Do not freeze.

Once opened use immediately and discard any unused solution.

Keep out of the sight and reach of children

Do not use your medicine after the expiry date (EXP) which is stated on the tube and outer carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Microlax contains

The active ingredients in Microlax are:

Sodium Citrate 450mg per 5ml and Sodium Lauryl Sulphoacetate 45mg per 5ml.

Other ingredients are: Sorbitol (E420), Sorbic acid (E200), Glycerol (E422) and Water.

What Microlax looks like and contents of the pack

Microlax is a colourless, thick, rectal solution contains small air bubbles, supplied in 5ml microenema tubes, with a nozzle. Each carton contains 4 or 50 tubes.

Product Authorisation holder:

Johnson & Johnson (Ireland) Limited
Airtown Road, Tallaght, Dublin 24
Ireland.

Manufacturer:

Microlax is made by:
Delpharm Orleans
5 avenue de Concy
45071, Orleans, Cedex 2
France.

This leaflet was revised August 2020.



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